Berinert

HMSACOM - Prior Authorization Request

CVS Caremark administers the prescription benefit plan for the patient identified. This patient's benefit plan requires prior authorization for certain medications in order for the drug to be covered. To make an appropriate determination, providing the most accurate diagnosis for the use of the prescribed medication is necessary. **Please respond below and fax this form to CVS Caremark toll-free at 1-866-237-5512**. If you have questions regarding the prior authorization, please contact CVS Caremark at **1-808-254-4414.** For inquiries or questions related to the patient's eligibility, drug copay or medication delivery; please contact the Specialty Customer Care Team: CaremarkConnect® 1-800-237-2767.

The recipient of this fax may make a request to opt-out of receiving telemarketing fax transmissions from CVS Caremark. There are numerous ways you may opt-out: The recipient may call the toll-free number at 877-265-2711, at any time, 24 hours a day/7 days a week. The recipient may also send an opt-out request via email to do_not_call@cvscaremark.com. An opt out request is only valid if it (1) identifies the number to which the request relates, and (2) if the person/entity making the request does not, subsequent to the request, provide express invitation or permission to CVS Caremark to send facsimile advertisements to such person/entity at that particular number. CVS Caremark is required by law to honor an opt-out request within thirty days of receipt.

Patient's Name: _____ **Date**: _____
Patient's ID: _____ **Patient's Date of Birth:** _____
Patient's Phone Number: _____
Physician's Name: _____
Specialty: _____ **NPI#:** _____
Physician Office Telephone: _____ **Physician Office Fax:** _____

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Additional Demographic Information:

Patient Weight: _____*kg*

Patient Height: _____*ft* _____*inches*

Indicate where the drug is being dispensed:

❑ Office ❑ Outpatient Hospital ❑ Ambulatory Surgical ❑ Inpatient Hospital
❑ Off Campus Outpatient Hospital ❑ Urgent Care ❑ Emergency Room ❑ Birthing Center
❑ Military Facility ❑ Skilled Nursing Facility ❑ Nursing Facility ❑ Hospice
❑ Inpatient Psychiatric ❑ Psychiatric Residential Treatment ❑ End Stage Renal Facility
❑ Psychiatric Facility ❑ Pharmacy ❑ Other

Indicate where the drug is being administered:

❑ Ambulatory surgical ❑ Home ❑ Inpatient Hospital
❑ Office ❑ Outpatient Hospital ❑ Pharmacy

Send completed form to: CVS Caremark Specialty Programs. Fax: 1-866-237-5512

 Berinert MR HMSACOM C21335-A, C12323-A – 01/2026.

Exception Criteria Questions:

A. Is the product being requested for the treatment of acute attacks of hereditary angioedema?
❑ Yes ❑ No *If No, skip to Criteria Questions*

B. The preferred products for your patient's health plan are icatibant and Ruconest.
Can the patient's treatment be switched to icatibant or Ruconest?
❑ Yes, *Please obtain Form for preferred product and submit for corresponding PA.*
❑ No

C. Is the patient less than 13 years of age? *If Yes, skip to Criteria Questions* ❑ Yes ❑ No

D. Is the patient 13 years of age or older but less than 18 years of age? ❑ Yes ❑ No *If No, skip to H*

E. Does the patient have a documented contraindication to Ruconest (i.e., a known or suspected allergy to rabbits or rabbit-derived products)? ***ACTION REQUIRED: If 'Yes', please attach supporting chart note(s).***
If Yes, skip to Criteria Questions ❑ Yes ❑ No

F. Is Berinert being requested for the treatment of laryngeal attacks?
If Yes, skip to Criteria Questions ❑ Yes ❑ No

G. Has the patient tried and experienced a documented inadequate response or intolerable adverse event to treatment with the preferred product (Ruconest)? ***ACTION REQUIRED: If 'Yes', please attach supporting chart note(s).*** ❑ Yes ❑ No *If Yes or No, Skip to Criteria Questions*

H. Has the patient tried and experienced a documented inadequate response or intolerable adverse event to icatibant AND a documented inadequate response, intolerable adverse event or contraindication to Ruconest (i.e., a known or suspected allergy to rabbits or rabbit-derived products)? ***ACTION REQUIRED: If 'Yes', please attach supporting chart note(s).***
If Yes, skip to Criteria Questions ❑ Yes ❑ No

I. Has the patient tried and experienced a documented inadequate response or intolerable adverse event to icatibant? ***ACTION REQUIRED: If 'Yes', please attach supporting chart note(s).*** ❑ Yes ❑ No

J. Is Berinert being requested for the treatment of laryngeal attacks? ❑ Yes ❑ No

Criteria Questions:

1. What is the diagnosis?
❒ Hereditary angioedema (HAE), *Continue to #2*
❒ Other, *Continue to #2*

2. Have other causes of angioedema been ruled out (e.g., angiotensin-converting enzyme inhibitor [ACE-I] induced angioedema, angioedema related to an estrogen-containing drug, allergic angioedema)?
❒ Yes, *Continue to #3*
❒ No, *Continue to #3*

3. Will the requested drug be prescribed by or in consultation with a prescriber who specializes in the management of hereditary angioedema (HAE)?
❒ Yes, *Continue to #4*
❒ No, *Continue to #4*

4. What is the clinical setting in which the requested medication will be used?
❒ Short-term preprocedural prophylaxis (i.e., prior to surgical or major dental procedures), *Continue to #10*
❒ Acute hereditary angioedema (HAE) attacks, *Continue to #30*
❒ Other, *No Further Questions*

Short-term preprocedural prophylaxis

10. What is the diagnosis?
❒ Hereditary angioedema (HAE) with C1 inhibitor deficiency or dysfunction confirmed by laboratory testing, *Continue to #11*
❒ HAE with normal C1 inhibitor confirmed by laboratory testing, *Continue to #12*
❒ Other, *No Further Questions*

11. Which of the following conditions does the patient have at the time of diagnosis? ***ACTION REQUIRED****: For any answer, attach laboratory test or medical record documentation confirming C1 inhibitor functional and antigenic protein levels*
❒ A C1 inhibitor (C1-INH) antigenic level below the lower limit of normal as defined by the laboratory performing the testAttach documentation and , *Continue to #50*
❒ A normal C1-INH antigenic level and a low C1-INH functional level (functional C1-INH less than 50% or C1-INH functional level below the lower limit of normal as defined by the laboratory performing the test) Attach documentation and, *Continue to #50*
❒ Other, *Continue to #50*

12. Which of the following conditions does the patient have at the time of diagnosis? ***ACTION REQUIRED****: For any answer, attach laboratory test or medical record documentation confirming normal C1 inhibitor. Based on the answer provided, attach genetic test or medical record documentation confirming F12, angiopoietin-1 plasminogen, kininogen-1 (KNG1), heparan sulfate-glucosamine 3-O-sulfotransferase 6 (HS3ST6), or myoferlin (MYOF) pathogenic variant testing or chart notes confirming family history of angioedema and the angioedema was refractory to a trial of high-dose antihistamine therapy*
❒ F12, angiopoietin-1, plasminogen, kininogen-1 (KNG1), heparan sulfate-glucosamine 3-O-sulfotransferase 6 (HS3ST6), or myoferlin (MYOF) pathogenic variant as confirmed by genetic testing Attach documentation and, *Continue to #50*
❒ BOTH of the following: 1) Angioedema refractory to a trial of high-dose antihistamine therapy (i.e., cetirizine at 40 mg per day or the equivalent) for at least one month AND 2) Family history of angioedema Attach documentation and, *Continue to #50*
❒ Other, *Continue to #50*

Acute Attacks

30. What is the diagnosis?
❒ Hereditary angioedema (HAE) with C1 inhibitor deficiency or dysfunction confirmed by laboratory testing, *Continue to #31*
❒ Hereditary angioedema (HAE) with normal C1 inhibitor confirmed by laboratory testing, *Continue to #32*
❒ Other, *No Further Questions*

31. Which of the following conditions does the patient have at the time of diagnosis? ***Action required***: For any answer, attach laboratory test or medical record documentation confirming C1 inhibitor functional and antigenic protein levels
❒ A C1 inhibitor (C1-INH) antigenic level below the lower limit of normal as defined by the laboratory performing the test, *Continue to #33*
❒ A normal C1-INH antigenic level and a low C1-INH functional level (functional C1-INH less than 50% or C1-INH functional level below the lower limit of normal as defined by the laboratory performing the test), *Continue to #33*
❒ Other, *Continue to #33*

32. Which of the following conditions does the patient have at the time of diagnosis? ***Action required***: For any answer, attach laboratory test or medical record documentation confirming normal C1 inhibitor.Based on the answer provided, attach genetic test or medical record documentation confirming F12, angiopoietin-1, plasminogen, kininogen-1 (KNG1), heparan sulfate-glucosamine 3-O-sulfotransferase 6 (HS3ST6), or myoferlin (MYOF) pathogenic variant testing or chart notes confirming family history of angioedema and the angioedema was refractory to a trial of high-dose antihistamine therapy
❒ F12, angiopoietin-1, plasminogen, kininogen-1 (KNG1), heparan sulfate-glucosamine 3-O-sulfotransferase 6 (HS3ST6), or myoferlin (MYOF) pathogenic variant as confirmed by genetic testing, *Continue to #33*
❒ BOTH of the following: 1) Angioedema refractory to a trial of high-dose antihistamine therapy (i.e., cetirizine at 40 mg per day or the equivalent) for at least one month AND 2) Family history of angioedema, *Continue to #33*
❒ Other, *Continue to #33*

33. Will the requested drug be used in combination with any other medication used for the treatment of acute HAE attacks (e.g., Ruconest, Firazyr, Kalbitor)?
❒ Yes, *Continue to #34*
❒ No, *Continue to #34*

34. Has the patient previously received treatment with the requested medication?
❒ Yes, *Continue to #35*
❒ No, *Continue to #51*

35. Has the patient experienced a reduction in severity and/or duration of attacks? ***Action Required***: If 'Yes', attach supporting chart note(s) demonstrating a reduction in severity and/or duration of attacks
❒ Yes, *Continue to #36*
❒ No, *Continue to #36*

36. Does the patient's attack frequency, attack severity, comorbid conditions and patient's quality of life warrant prophylactic therapy?
❒ Yes, *Continue to #37*
❒ No, *Continue to #51*

37. Has prophylactic treatment been considered?
❒ Yes, *Continue to #51*
❒ No, *Continue to #38*

38. Please provide a brief rationale as to why prophylactic treatment has not been considered.

_____
_____, *Continue to #51*

Quantity Limit (weight-based dose)

Preprocedural prophylaxis

50. What is the patient's body weight?
❒ 100 kg (220.5 lbs) or less, *No Further Questions*
❒ Greater than 100 kg (220.5 lbs), *No Further Questions*

Acute attacks

51. What is the patient's body weight?
❒ 100 kg (220.5 lbs) or less, *No Further Questions*
❒ Greater than 100 kg (220.5 lbs), *No Further Questions*

I attest that this information is accurate and true, and that documentation supporting this information is available for review if requested by CVS Caremark or the benefit plan sponsor.

X_____
Prescriber or Authorized Signature **Date (mm/dd/yy)**